DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
ATL-35 M3583:97

60 8th Street, N.E.
Atlanta, Georgia 30309

March 24, 2000

VIA FEDERAL EXPRESS

WARNING LETTER
(00-ATL-35)

Mr. Jared R. Wheat, President
Hi-Tech Pharmaceuticals
D/B/A United Metabolic Research Center
5675 Jimmy Carter Blvd., Suite 720
Norcross, GA 30071

Dear Mr. Wheat:

This letter is in reference to your firm's marketing and distribution of Betadrene-SR. Labeling for this product contains therapeutic claims which cause the product to be a drug (section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)). Labeling is not limited to the immediate product containers, but includes all promotional literature which you distribute in connection with your product.

Objectionable claims for Betadrene-SR include references to obesity and to the International Journal of Obesity, reference to (time-release) the overall dissolution rate and drug delivery, and comparison of the product to prescription diet drugs including Phen-Fen and Redux.

Betadrene-SR is a "new drug" (section 201(p) of the Act). Therefore, it may not be legally marketed in this country without an approved New Drug Application (section 505(a) of the Act).

This drug is also misbranded because its labeling fails to bear adequate directions for the conditions for which it is offered (section 502(f)(1) of the Act and its labeling is false and misleading because it suggests that this product is safe and effective for its intended use, when in fact, this has not been established (section 502(a) of the Act).

This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct

these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Compliance Officer Sheryl R. Cruse at the above letterhead address.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District